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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,212	12/15/2000	Klaus Neuer	4-118-8353B/C1	9685

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EXAMINER
BERMAN, ALYSIA

ART UNIT	PAPER NUMBER
1617	11

DATE MAILED: 05/21/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/738,212	Applicant(s) NEUER ET AL.	
	Examiner Alysia Berman	Art Unit 1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21-33* is/are pending in the application.

4a) Of the above claim(s) *31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21-30 and 33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. *09/077,231* .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Receipt is acknowledged of the amendment filed February 27, 2002 with a certificate of mailing date of January 16, 2002. Claims 1-19 have been canceled. Claims 21-33 have been added and are pending.

Election/Restrictions

2. Newly submitted claims 31 and 32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the newly submitted claims are directed to a method of using a hard gelatin capsule, which was not originally presented or examined.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 31 and 32 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claim 33 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claim 33 is vague and indefinite because it is unclear what applicant intends to claim for component (e). Is component (e) either a combination of ricinoleic acid

glyceride(s) and multiply unsaturated fatty acid glycerides or castor oil or is it a mixture of ricinoleic acid glyceride(s) with multiply unsaturated fatty acid glycerides or a mixture of ricinoleic acid glyceride(s) with castor oil? Additionally, in relation to what are the proportions of multiply unsaturated fatty acid glycerides smaller?

Claim Rejections - 35 USC § 102

6. The 35 U.S.C. 102(b) rejections of claims 1, 2, 5, 7-10 and 17-19 over US 5,047,396 (396) and US 5,342,625 (625) are withdrawn. Neither reference teaches all of the limitations of the instant independent claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 21-30 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,047,396 (396) in combination with US 5,342,625 (625).

US '396 discloses a pharmaceutical composition comprising 1 part cyclosporin, 8 to 13 parts of a polyethylene glycol saturated hydroxy fatty acid, and 4 to 10 parts of a mono- or polyvalent alcohol (abstract). Cyclosporin A is disclosed at column 2, lines 44-47. Alcohols that may be present as co-solvents in the composition are ethanol and propylene glycol (col. 3, lines 1-5). Various excipients can be used in the formulation (col. 3, lines 15-16). Example 1 teaches 65 g of Solutol® HS 15 (polyethylene glycol-660-12-hydroxystearate), 30 ml of ethanol and 5 g of cyclosporin A. Ethanol is added to 100 ml. The composition of example 1 comprises 65% polyethylene glycol-660-12-hydroxystearate, 5% cyclosporin A and 30% ethanol. See also claim 6 for polyethylene glycol-660-12-hydroxy stearate and claim 7 for ethanol and propylene glycol. US '396 does not teach the composition in a capsule.

US '625 is directed to pharmaceutical compositions comprising cyclosporins (title). For Cyclosporin A and additional cyclosporins, see column 2, line 61 to column 3, line15. The composition comprises a hydrophilic phase, a lipophilic phase and a surfactant (col. 6, lines 45-50). For propylene glycol as the hydrophilic phase, see column 7, lines 21-25. For additional alcohols in the hydrophilic phase such as ethanol, see column 8, lines 25-35. For polyoxyethylene stearic acid esters as surfactants, see column 9, lines 40-44 and column 10, lines 31-32. US '625 teaches at column 12, lines 16-17 that the composition may contain a single surfactant, i.e. a polyoxyethylene stearic acid ester. For hard and soft gelatin capsules, see column 16, lines 25-28. For

ratios of components, see column 17, line 50 to column 18, line 20. The ratio of cyclosporin (a) to hydrophilic phase (c) is 1:0.2-10 p.p.w. (col. 17, lines 50-54). The ratio of cyclosporin to surfactant (b) is 1:0.5-20 (col. 18, lines 13-20). Therefore, the ratio of (a):(b):(c) is 1: 0.5-20: 0.2-10, which overlaps the instantly claimed ratios. US '625 teaches fatty acid triglycerides (triesters of fatty acids) as the lipophilic phase at column 8, lines 56-65 and mono-, di- and mono/diglycerides as surfactants at column 11, lines 36-52.

US '396 teaches a composition containing cyclosporin A, polyethylene glycol-660-12-hydroxystearate, ethanol and propylene glycol. US '625 teaches that compositions containing a cyclosporin, a polyethoxylated hydroxy fatty acid ester surfactant, ethanol and propylene glycol can be provided in a hard gelatin capsule.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '396 in a hard gelatin capsule as taught by US '625 with the reasonable expectation of obtaining a cyclosporin composition that provides convenient oral administration and improved bioavailability.

Double Patenting

10. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-30 of copending Application No. 09/690400. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed to compositions comprising cyclosporin, a C_2-C_3 alcohol and a surfactant. The applications differ in that 09/690400 is claiming also a mixed mono-, di-, triglyceride. The instant application discloses mono-, di-, and triesters of fatty acids for use in the compositions. See claim 3. Glycerides are esters. It would have been obvious to one of ordinary skill in the art at the time of the invention to make the composition of the instant application and add mixed mono-, di-, triglyceride as disclosed in 09/690,400 expecting to obtain a oral dosage form containing cyclosporin .

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 2 of copending Application No. 09/605512. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a composition comprising cyclosporin a polyethoxylated hydroxy fatty acid ester surfactant and an alcohol.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claims 21-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3, 5-8, 15, 17, 19, 24, 26 and 28 of copending Application No. 09/547802. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are claiming a composition comprising cyclosporin, an alcohol and a surfactant.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

14. Applicant's arguments filed February 27, 2002 have been fully considered but they are not persuasive.

15. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, US '396 teaches the composition instantly claimed and US '625 teaches that compositions like those instantly claimed and disclosed in US '396 can be provided in hard gelatin capsules. US

'396 also teaches at column 1 that it is known in the art to orally administer cyclosporin. The motivation to combine the references is to provide convenient oral administration and improved bioavailability of a cyclosporin composition.

16. No arguments were presented against the double patenting rejections.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703-308-4638. The examiner can normally be reached Monday through Friday between 9:00 am and 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, can be reached on 703-308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 or 703-872-9307 for after-final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234 or 703-308-1235.

Alysia Berman
Patent Examiner
May 10, 2002

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